

### REMARKS

Applicant has reviewed the Office Action dated December 15, 2005 (hereinafter "Office Action"), and the references cited therewith.

Claims 1, 4, 9, 10, 11, 18, and 24 are amended, no claims are canceled, and claims 30 and 31 are added; as a result, claims 1-31 are now pending in this application. Applicant submits that the amendments and additions to the claims are fully supported by the specification as originally filed, and no new matter has been added.

Applicant hereby respectfully requests further examination and reconsideration of the application in view of the following remarks.

#### §102 Rejection of the Claims

Claims 1-7, 9-13, 15-20, 22, 24-26 and 29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cobian et al. (U.S. Patent No. 5,796,044). Applicant respectfully traverses such rejections on the basis that the Office Action failed to make out a *prima facie* case of anticipation on at least the following grounds.

Anticipation requires that the claimed subject matter be *identically* disclosed in the prior art. *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972)(emphasis added). The reference relied upon must teach or suggest *all* the elements and/or limitations of the claims. *See In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)(stating "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art")(emphasis added).

#### *Claims 1-7 and 9-10:*

Applicant submits the Office Action has failed to make out a *prima facie* case of anticipation for claims 1-7 and 9-10 because, among other things, all claim elements and/or limitations cannot be found in the cited reference (Cobian), as required by *In re Arkley* at page 526.

#### *Claims 1, 2, 3, 6, and 7:*

Among other things, Applicant cannot find in the cited portions of Cobian, "[a] lead assembly comprising . . . the second conductor disposed within the first conductor, the second

conductor including one or more filars having an outer filar surface having an insulative coating disposed directly thereon such that a cross-section of the outer filar surface is surrounded by the insulative coating,” as recited in Applicant’s claim 1. Rather, as the Office Action points out, Cobian recites “a coiled wire conductor that is sheathed loosely within a coiled insulative sheath . . . allowing a gap or space to be present between the exterior surface of the coiled wire conductor and the adjacent interior surface of the insulative sheath.” (Abstract; *see also* col. 5, lines 12-60). Cobian further recites “[i]n each of the above-described embodiments, it is assumed that all of the coiled wire conductors are insulated by a coiled insulative sheath that loosely receives it.” (Col. 11, lines 62-64).

Because all elements and/or limitations of Applicant’s claim 1 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 1. Claims 2-10 are dependent on claim 1 and are patentable over Cobian for the reasons stated above, in addition to the elements in such claims.

*Claim 4:*

In addition to the foregoing reasons set forth supporting a finding of patentability of claims 1-10 (of which claim 4 is included), Applicant cannot find in the cited portions of Cobian a lead assembly “wherein [an] insulative sleeve comprises a tube of polyurethane, polyimide, or polysiloxane urethane disposed between the first conductor and the second conductor,” as recited in Applicant’s claim 4. Rather, as pointed out by the Office Action, Cobian merely recites “[a] further separating sheath 38 is provided intermediate the inner insulative sheath 27 and the outer insulative sheath 22.” (Col. 11, lines 4-6; *see also* Office Action, page 4).

Because all elements and/or limitations of Applicant’s claim 4 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 4.

*Claim 5:*

In addition to the foregoing reasons set forth supporting a finding of patentability of claims 1-10 (of which claim 5 is included), Applicant cannot find in the cited portions of Cobian a lead assembly “wherein [an] insulative sleeve is comprised of a non-silicone material [disposed between the first conductor and the second conductor],” as recited in Applicant’s claim 5. In

rejecting claim 5, the Office Action cites one or more portions in Cobian referring to “coiled insulative sheaths 42, 82, 84” as opposed to “separating sheath 38.” (*See* col. 5, lines 57-67; col. 11, line 5; col. 12, lines 42-50).

Because all elements and/or limitations of Applicant’s claim 5 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 5.

*Claims 9-10:*

In addition to the foregoing reasons set forth supporting a finding of patentability of claims 1-10 (of which claims 9 and 10 are included), Applicant cannot find in the cited portions of Cobian a lead assembly “further comprising a coating of insulation disposed directly on an outer filar surface of the first conductor,” as recited in Applicant’s claim 9. Rather, as the Office Action points out, Cobian recites “[a] coiled insulative sheath loosely receiv[ing] the first coiled wire conductor therein . . . and . . . a second insulative sheath . . . for loosely receiving the second coiled wire conductor therein.” (Col. 5, lines 30-31, 38, 41-42).

Because all elements and/or limitations of Applicant’s claim 9 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 9. Claim 10 is dependent on claim 9 and is patentable over Cobian for the reasons stated above, in addition to the elements in such claims.

*Claims 11-13 and 15-17:*

Applicant submits the Office Action has failed to make out a *prima facie* case of anticipation for claims 11-13 and 15-17 because, among other things, all claim elements and/or limitations cannot be found in the cited reference (Cobian), as required by *In re Arkley* at page 526.

*Claims 11-13 and 15-17:*

Among other things, Applicant cannot find in the (Office Action) cited portions of Cobian, “[a] lead assembly comprising . . . the second conductor disposed within the first conductor, a coating of insulation disposed directly on an outer filar surface of one or more filars of the first conductor or the second conductor such that a cross-section of the outer filar surface

of the first conductor or the second conductor is surrounded by the insulative coating,” as recited in Applicant’s claim 11. To this end, Applicant hereby incorporates by reference the relevant arguments stated above with respect to claims 1 and 9.

Because all elements and/or limitations of Applicant’s claim 11 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 11. Claims 12-17 are dependent on claim 11 and are patentable over Cobian for the reasons stated above, in addition to the elements in such claims.

*Claims 18-20 and 22:*

Applicant submits the Office Action has failed to make out a *prima facie* case of anticipation for claims 18-20 and 22 because, among other things, all claim elements and/or limitations cannot be found in the cited reference (Cobian), as required by *In re Arkley* at page 526.

*Claims 18-19:*

Among other things, Applicant cannot find in the cited portions of Cobian, “[a] method comprising . . . disposing insulation directly on the second outer filar diameter such that a cross-section of the outer filar diameter is surrounded by an insulative coating,” as recited in Applicant’s claim 18. To this end, Applicant hereby incorporates by reference the relevant arguments stated above with respect to claim 1.

Because all elements and/or limitations of Applicant’s claim 18 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 18. Claims 19-23 are dependent on claim 18 and are patentable over Cobian for the reasons stated above, in addition to the elements in such claims.

*Claim 20:*

In addition to the foregoing reasons set forth supporting a finding of patentability of claims 18-23 (of which claim 20 is included), Applicant cannot find in the cited portions of Cobian a method “where the first conductor includes a first outer filar diameter, and the method further comprises disposing insulation on the first outer filar diameter of the first conductor,” as

recited in Applicant's claim 20. To this end, Applicant hereby incorporates by reference the relevant arguments stated above with respect to claim 9.

Because all elements and/or limitations of Applicant's claim 20 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 20.

*Claim 22:*

In addition to the foregoing reasons set forth supporting a finding of patentability of claims 18-23 (of which claim 22 is included), Applicant cannot find in the cited portions of Cobian a method "further comprising disposing polyurethane tubing between the first conductor and the second conductor," as recited in Applicant's claim 22. To this end, Applicant hereby incorporates by reference the relevant arguments stated above with respect to claim 4

Because all elements and/or limitations of Applicant's claim 22 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 22.

*Claims 24-26 and 29:*

Applicant submits the Office Action has failed to make out a *prima facie* case of anticipation for claims 24-26 and 29 because, among other things, all claim elements and/or limitations cannot be found in the cited reference (Cobian), as required by *In re Arkley* at page 526.

*Claims 24-26:*

Among other things, Applicant cannot find in the cited portions of Cobian, "[a] method comprising . . . providing a second conductor having a coiled configuration having a second outer coil diameter, and the second conductor having a second outer filar diameter including an insulative coating disposed thereon such that a cross-section of the second outer filar diameter is surround by the insulative coating," as recited in Applicant's claim 24. To this end, Applicant hereby incorporates by reference the relevant arguments stated above with respect to claim 1.

Because all elements and/or limitations of Applicant's claim 24 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 24.

Claims 25-29 are dependent on claim 24 and are patentable over Cobian for the reasons stated above, in addition to the elements in such claims.

*Claim 29:*

In addition to the foregoing reasons set forth supporting a finding of patentability of claims 24-29 (of which claim 29 is included), Applicant cannot find in the cited portions of Cobian a method “where the first conductor includes a first outer filar diameter, and the method further comprises disposing insulation on the first outer filar diameter of the first conductor,” as recited in Applicant’s claim 29. To this end, Applicant hereby incorporates by reference the relevant arguments stated above with respect to claim 9.

Because all elements and/or limitations of Applicant’s claim 29 cannot be found in the cited portions of Cobian, Applicant respectfully requests withdrawal of the rejection of claim 29.

§103 Rejection of the Claims

Claims 8 and 14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian et al. (U.S. Patent No. 5,796,044) in view of Helland et al. (U.S. Patent No. 5,545,201). Claims 21 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian et al. (U.S. Patent No. 5,796,044) in view of Altman et al. (U.S. Patent No. 5,845,396). Claims 23, 27 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobian et al. (U.S. Patent No. 5,796,044) in view of Nelson et al. (U.S. Patent No. 6,249,708). Applicant respectfully traverses such rejections and submits that the Office Action has failed to make out a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, three criteria must be met.

First, there must be some suggestion or motivation, either in the cited reference(s), or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d (BNA) 1438 (Fed. Cir. 1991)). According to *In re Lee*, “there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant.” 61 USPQ2d 1430 (Fed. Cir. 2002)(citing *In re Fine*), see also *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir.

1984)(holding “[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination”).

As further stated by *In re Lee*, the “factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority.” *In re Lee* (emphasis added). “We do not ‘pick and choose among the individual elements of assorted prior art references to recreate the claimed invention,’ but rather, we look for ‘some teaching or suggestion in the references to support their use in the particular claimed combination.’” *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991). Motivation to combine requires desirability, not merely a trade-off. Trade-offs often concern what is feasible, not what is necessarily desirable. Motivation to combine requires the latter. *Winner International Royalty Corp. v. Wang*, 202 F.3d 1340, 53 U.S.P.Q.2d 15080 (Fed. Cir.), cert. denied, 530 U.S. 1238 (2000).

A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986).

The examiner must provide a *specific reason* to support an obviousness rejection. *Ex parte Humphreys*, 24 USPQ2d 1255 (BPAI 1992). An examiner’s assertion that a modification proposed is “an obvious matter of design choice” is an unsupported conclusion – not a reason upon which to base a rejection. See *In re Garrett*, 33 BNA PTCJ 42 (November 13, 1986); see also *In re Gal*, 980 F.2d 717, 25 USPQ2d 1076 (Fed. Cir. 1992)(rejecting an “obvious design choice” rejection wherein the claimed structure and its function are different from the prior art).

Second, the prior art reference(s) must teach or suggest all of the claim elements and/or limitations. MPEP § 2142.

Third, there must be a reasonable expectation of success. MPEP § 2142.

*Claims 8 and 14:*

Applicant submits the Office Action has failed to make out a *prima facie* case of obviousness for claims 8 and 14 because, among other things, not all claim elements and/or limitations can be found in Cobian nor Helland (either individually or in combination), as required by M.P.E.P. § 2142.

In addition to the foregoing grounds set forth supporting the patentability of Applicant's claims 1-10 (of which claim 8 is included) and claims 11-17 (of which claim 14 is included), Applicant cannot find in the cited portions of Cobian nor Helland a lead assembly "further comprising a means for facilitating rotation of the second conductor relative to the first conductor," as recited in Applicant's claim 8, nor a lead assembly "wherein the second conductor is rotatable relative to the first conductor," as recited in Applicant's claim 14. Rather, Helland (wherein the Office Action submits the missing subject matter may be found) recites "the active fixation helix . . . is secured to a conductive plug 176 . . . [the latter of which] may be movable or fixed with respect to the lead body 122 and rigid insulating element 180." (Col. 5, lines 9-13). Applicant submits that the moving of conductive plug 176 does not necessary require "a means for facilitating rotation of the second conductor relative to the first conductor" or that "the second conductor is rotatable relative to the first conductor" as claimed by Applicant.

Because neither Cobian nor Helland teaches or suggests all of the claimed subject matter of Applicant's claims 8 and 14, Applicant respectfully requests withdrawal of the rejection of such claims.

*Claim 21:*

Applicant submits the Office Action has failed to make out a *prima facie* case of obviousness for claim 21 because, among other things, not all claim elements and/or limitations can be found in Cobian nor Altman (either individually or in combination), as required by MPEP § 2142, and because there is legally insufficient motivation to combine such references, as required in *In re Lee*.

In addition to the foregoing grounds set forth supporting the patentability of Applicant's claims 18-23 (of which claim 21 is included), Applicant cannot find in the cited portions of Cobian nor Helland a method "further comprising disposing polyimide tubing between the first



conductor and the second conductor,” as recited in Applicant’s claim 21. Rather, Altman (wherein the Office Action submits the missing subject matter may be found) recites “[a] method for manufacturing [a] . . . coiled cable lead . . . [wherein] each cable is coated with a fluoropolymer, polyimide or polyurethane coating and placed in a winder apparatus.” (Col. 2, lines 34-36). What is claimed by Applicant in claim 21 is an insulative member disposed between the first conductor and the second conductor, which is in addition to insulation on the coiled conductor(s).

Furthermore, Applicant cannot find any motivation to combine the teachings of Cobian with the teaching of Altman to make the specific combination that was made by Applicant in claim 21, as required by *In re Lee*. The Office Action must provide a specific reason to support an obvious rejection, e.g., a reason which is clear and particular and not a broad conclusory statement; however, no such reason has been provided. The assertion in the Office Action states that substituting one known lead insulating material for another would have been an obvious alternative design choice in order to effectively insulate the conductor so electrical signals associated with the heart can be accurately sensed and delivered. (Office Action, pages 3-4). Applicant submits that such assertion *prima facie* fails to satisfy the requirements of 35 U.S.C. § 103, as it fails to suggest a motivation to make a material substitution.

Because neither Cobian nor Altman teaches or suggests all of the claimed subject matter of Applicant’s claim 21, and no legally sufficient motivation to combine the subject matter of such references has been provided, Applicant respectfully requests withdrawal of the rejection of claim 21.

*Claims 23 and 27-28:*

Applicant submits the Office Action has failed to make out a *prima facie* case of obviousness for claims 23 and 27-28 because, among other things, there is legally insufficient motivation to combine Cobian and Nelson, as required in *In re Lee*.

In addition to the foregoing grounds set forth supporting the patentability of Applicant’s claims 18-23 (of which claim 23 is included) and claims 24-29 (of which claims 27 and 28 are included), Applicant submits that using Cobian and Nelson alone (e.g., without the use of the Applicant’s disclosure), one of ordinary skill in the art would not have been motivated to

combine the teachings of such references to produce a method “further comprising heat shrinking PTFE or ETFE on the second outer coil diameter,” as recited in Applicant’s claims 23 and 27.

As one example, Cobian and Nelson teach against being combined with one another. Cobian recites that “all of the coiled wire conductors are insulated by a coiled insulative sheath that loosely receives it.” (*See, e.g.*, col. 11, lines 62-64). Cobian subsequently recites “[a]dvantageously, the coiled wire insulative sheaths loosely receiving the coiled wire conductors decrease[s] the probability that defects in the coiled wire insulative sheath will result in mechanical fracture or deterioration of the lead conductor or unacceptable changes in electrical resistance.” (Col. 6, lines 1-5). In brief, Cobian relies on a gap between the insulative sheaths and the conductors to enhance the overall survivability of a lead. On the other hand, the cited portions of Nelson recites “PTFE tubing 38 is heat shrunk onto the inner coil 34.” (Nelson, col. 7, lines 46-48; *see also* Office Action, page 4). As can be seen from FIG. 10 of Nelson and the associated aforementioned text, the heat shrinking of Nelson teaches away from leaving a gap, such as that relied on in Cobian, between tubing 38 and inner coil 34. (*Id.*, FIG. 10).

As another example, the Office Action appears to pick and choose among individual elements of assorted references to recreate the claimed invention without some teaching or motivation in the references to support their use in the particular claimed combination, as prohibited by *Symbol Technologies, Inc.* 935 F.2d 1569. Motivation to combine requires desirability, not merely a trade-off. *Winner International Royalty Corp.*, 202 F.3d 1340.

Because no legally sufficient motivation to combine the subject matter of Cobian with the subject matter of Nelson has been provided, Applicant respectfully requests withdrawal of the rejections of claims 23 and 27. Claim 28 is dependent on claim 27 and is patentable for the reasons stated above, in addition to the elements in such claim.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

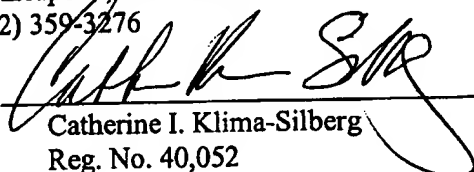
Respectfully submitted,

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